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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/186,810	11/05/1998	WENDA C. CARLYLE	1416.25US02	2290

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EXAMINER

PREBILIC, PAUL B

ART UNIT PAPER NUMBER

3738

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/186,810

Applicant(s)

CARLYLE ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-10,13-15,28,29 and 33-46 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 28,29,33 and 41-44 is/are allowed.
6) ☐ Claim(s) 1,3,4,8-10,13,15,34,35 and 38-46 is/are rejected.
7) ☒ Claim(s) 14,36 and 37 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8, 10, 13, 15, 34, 35, and 38-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 14, 21, and 29 of copending Application No. 09/014,087. The present claims are obvious over the copending claims because the same embodiment is set forth herein such that the claims set read on each other and are clearly obvious in view of each other.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, 9, 15, and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al (US 5,308,641) where the substrate as claimed is the polyalkylimine-coated tissue or other base material of Cahalan, and the growth factors are coated via glutaraldehyde (a difunctional aldehyde crosslinking agent) to it; see especially column 4, lines 20-43 and column 6, lines 8-28 and the abstract, column 4, lines 20-43, and column 6, lines 8-28. Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of a normal cell layer"; see column 1, lines 33-43. For this reason, it stimulates the "association of viable cells with the substrate" as claimed.

Regarding claim 15, Applicants are directed to column 4, lines 36-43 where some of the same biomedical devices are disclosed as substrates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Goldstein (US 5,613,982). Cahalan discloses medical devices/implants where the crosslinking agent glutaraldehyde attaches the growth factor biomolecule and to the substrate-spacer. Cahalan's solid surface can be made of human or animal tissues (see column 4, lines 32-33), but Cahalan lacks the types of tissues claimed.

However, Goldstein teaches that it was known to make similar medical devices/implants out of heart valves, pericardial tissue and the like; see the whole document, especially column 3, lines 14-24.

Therefore, it is the Examiner's position that it would have been obvious to use heart valve or pericardial tissue for Cahalan's solid surface in order to reduce the risk of disease transmission and cost over using human tissue. Furthermore, it would have been obvious to use these tissues for the same reasons that Goldstein desires the same.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al in view of Bayne et al (EP 0476983).

With regard to claim 13, Cahalan fails to disclose the use of VEGF as claimed even though it discloses utilizing many other growth factors therewith. Bayne teaches that it was known to use VEGF as the growth factor in a similar fashion within the same art; see the see page 8, lines 14-26.

Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to use VEGF as the growth factor of Cahalan so that the implant could be successfully implanted in vascular regions of the body.

Allowable Subject Matter

Claims 28, 29, 33, and 41-44 are allowed over the prior art of record.

Claims 14, 36, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are not considered persuasive.

With regard to the traversal of the double patenting rejection, the Examiner notes that no reasons were given for the distinctness of the two claims sets; only the Applicants opinion was given. For this reason, no further comment is deemed necessary.

In response to the argument traversing the Cahalan rejection that Cahalan lacks direct crosslinking of the growth factor to the substrate without a spacer molecule, the Examiner asserts that the claims do not preclude a spacer molecule and that the claims are at least read on by Cahalan. For this reason, this argument is not commensurate with the scope of the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue that the crosslinking agent is used to attach polyalkylimine to the surface not the biomolecules. In reviewing Cahalan, the Examiner found the opposite to be true. Rather, the crosslinking agent (an aldehyde) crosslinks the surface and provides aldehyde functionalities to the surface to bind biomolecules; see column 4, line 66 to column 5, line 3 and the abstract. Furthermore, the Examiner asserts that the fact that Cahalan is concerned with attaching spacer molecules to a substrate does not mean the disclosure thereof does not anticipate the claim language.

On page 3 of the response, Applicants excerpt a portion of the specification that is said to support their contention that the claim language is not met. Upon careful review of this excerpt, **it was determined that the Applicants have misquoted the specification by leaving out an important word.** In particular, the excerpt failed to include the word "aldehyde" before "functionality." This omission makes it unclear what functionality is involved in the attaching the biomolecule to the substrate. Since the claims require an aldehyde group of the crosslinking agent to link the growth factor to the substrate, this omission is significant. With the term "aldehyde", it is clear that the claim language is fully met.

Applicants also suggest that Cahalan does not teach stimulation of the association of viable cells to the substrate as claimed. However, Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of a normal cell layer"; see column 1, lines 33-43. For this reason, the claim language is considered to be fully met in this regard.

Applicants traverse the use of Goldstein and Bayne as teaching references because they say there Cahalan does not teach all the elements of claim 1. However, it is clear that all the elements of claim 1 are present in Cahalan. For this reason, there is no good reason to withdraw the rejections utilizing Goldstein or Bayne.

In response to Applicants' argument that Sharpe is not directed to the presently claimed invention, the Examiner has withdrawn this rejection as a result of Applicants amendment to claim 41.

In response to the traversal of Cahalan that Cahalan does not teach all the claim limitations of binding the growth factor directly to the substrate, the Examiner respectfully disagrees with this argument and has explained that the substrate merely contains a base material with the polyalkylimine bonded to it. For this reason, the claims are at least read on by Cahalan.

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action unless such applications are stored in image format (i.e. IFW). Generally, those applications filed or amended after July 1, 2003 are image file wrapper (IFW) applications.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (571) 272-4758. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738